what our claims might be over oral morphine and their respective sources of support." Then the sentence right under that says, "OxyContin claims over oral morphine/support sources."

What did you mean by "support sources"?

A. I meant those factors that under certain circumstances -- well, they differ. Some support sources differ from others. Support sources, some of those are properties of OxyContin, some are information that we gleaned from studies. Some of those are outcomes that one might find under certain circumstances that support the concept.

Q. The concept of the claim ease of titration?

A. Most efficiently titratable, yes.

Q. Let's look at those. The first one is "short half-life of elimination." It says, "This is well established in the literature." What is the source of support for the statement "short half-life of elimination"?

A. The half-life of oxycodone was known at the time to be a short elimination half-life.

Q. What is there to support the short elimination half-life of OxyContin?

A. Excuse me?

Q. What is there to support the short elimination half-life of OxyContin?

A. There is a published report based upon a study designed to

determine elimination half-life.

Q. The next topic is "rapidly attains steady-state plasma oxycodone levels." Could you explain that, please.

A. Yes. It is a basic tenet of pharmacology that if the drug has a short elimination half-life, it will attain steady-state quicker than drugs of long elimination half-lives. In addition to that principle, I was being guided by the results of our steady-state studies, where we established that within about a day patients had attained steady-state concentrations with repeated doses of OxyContin.

Q. How does that support the claim most efficiently titratable long-acting analgesic?

A. It is really not clinically advisable to judge whether or not a patient is receiving the right dose of a drug until the patient attains steady state. Ideally, a doctor would like to prescribe medication and then ask the patient to call him in the morning. I call this kind of drug that attains steady state rapidly a call-me-in-the-morning kind of drug. The physician can tell the patient, I am going to prescribe the medication, I'm not sure it is the right dose, call me in the morning, tell me how you're doing.

If a drug has attained steady state by the next day, which drugs of short elimination half-life do, then the physician can make the judgment next day as to what the balance between pain control and side effects are, knowing that that is

what is going to remain to be the case with repeated dosing after that, that it shouldn't change unless something else changes.

If a drug, however, has a long elimination half-life, it might be days to weeks, quite variable, so that the doctor doesn't know when the patient is going to attain steady state, doesn't know when he can rationally determine when the patient is at a point where he can change the dose safely or not.

Getting to state quickly is clearly a part of being easily titratable or efficiently titratable. If it takes a day or two, that is much better, more efficient, than if it takes a week or two and not knowing within that time frame whether the patient is at steady state or not and if the dose can be raised or not.

Q. The next support says, "rapidly attain stable pain control." How does that support the claim most easily titratable long-acting strong analgesic?

A. Along with achieving steady state quickly, there is the likelihood of achievement of a balance between efficacy and side effects that is going to remain to be the case, as is indicated there in the first sentence. This is a function of what would happen with any drug of this type that has a short half-life as compared to those that don't have a short half-life, like the ones listed on the bottom there, methadone, lavorfanol, etc.

Q. What was the source for this statement "rapidly attains stable pain control"?
A. It is understood with these drugs that if you have a short half-life, they get you to steady state quickly. Unless the patient's state is changing dramatically for other reasons, you are going to achieve pain control fairly quickly. We saw this in the context of our studies with two drugs that did have short elimination half-lives. But what we are saying here is that that is the case to begin with in comparison to drugs that have much longer elimination half-lives.
Q. The next entry is "rapidly titratable to the 'right dose.'" What is the source for that statement?
A. That follows from the above.
Q. From the 3A, B, C above?
A. Yes.
Q. "High oral bioavailability" is next?
A. Yes.
Q. What is the source for that statement?
A. The published literature showing that morphine has a low oral bioavailability and oxycodone has a high oral bioavailability.
Q. Let's look at the next page, please. The next entry, F, is "less variation in bioavailability." What is the source for that statement?
A. At the time that I wrote that, I did not have a source

other than the insight that a drug with a high oral bioavailability had to have a narrower range in that bioavailability as compared to a drug with low oral bioavailability.

Q. This is what you testified to about yesterday?

A. Yes.

Q. G says, "less variation in plasma oxycodone concentrations." I gather the source of that is the preceding paragraph?

A. Yes.

Q. Let's look at H, "less variation in pain control." What is the source for that statement?

A. The sections that come before it. It would be an outcome of what I previously described.

Q. Let's look at I, "fewer patients under- or overdosed upon initiation of OxyContin." What is the source of that statement?

A. This is a prediction actually based on the arguments that come before it, the combination of the high oral bioavailability and short half-life with the range of oral bioavailability being substantially less and variability in blood levels therefore being substantially less. You therefore should be able -- the outcome of that would be if, when a doctor starts out a patient on OxyContin as compared to let's say MS Contin, because the blood level range is narrower, there

Q. You were asked on cross-examination about controlled-release codeine and whether it should have been cited to the patent office. Do you recall that?
A. Yes.
Q. What type of pain is codeine prescribed for?
A. More moderate pain. More moderate pain.
Q. You were also asked about controlled-release dihydrocodeine. Do you recall that?
A. Yes.
Q. What type of pain is dihydrocodeine prescribed for?
A. Moderate pain.
Q. Are either controlled-release codeine or controlled-release dihydrocodeine, to your knowledge, prescribed to treat moderate to severe pain?
A. No.

MS. LORING: Your Honor, I have no further questions for Dr. Kaiko. I do have two exhibits, though.

THE COURT: Go ahead.

MS. LORING: Yesterday, when I was offering exhibits in Dr. Kaiko's direct case, I omitted Defendant's Exhibit 3234. I don't believe there is any objection to that. I would also like to offer Plaintiff's Exhibit 21.

THE COURT: Hearing no objection --

MR. FILARDI: No objection.

THE COURT: Admitted.

(Plaintiff's Exhibit 21 received in evidence)

(Defendant's Exhibit 3234 received in evidence)

THE COURT: Is there any recross?

MR. FILARDI: No recross, your Honor. But if I may, when I read the end of my cross, your Honor, I read the exhibits and I missed 4366. May I offer it at this time?

THE COURT: Admitted without objection. I take it that also was one that you used on cross-examination?

MR. FILARDI: Indeed, yes.

MS. LORING: No objection, your Honor.

THE COURT: Admitted.

(Defendant's Exhibit 4366 received in evidence)

THE COURT: You may step down, sir.

(Witness excused)

THE COURT: Next witness for plaintiff, please.

MS. LORING: Plaintiffs called Benjamin Oshlack.

Your Honor, if I may, while they are retrieving Mr. Oshlack, I have some exhibits to offer. I don't believe there is any objection to these. If I may read them?

THE COURT: Yes, ma'am.

MS. LORING: Plaintiff's Exhibits 14, 19, 451, 453, 455, 457, 459, 461, 463, 465, 467, 469, 476, 480, 491, 492, 493,498, 510A, 511A, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 758, 759, 866, and 1009 we offer for the truth.

THE COURT: Hearing no objection, admitted.

(Plaintiff's Exhibits 14, 19, 451, 453, 455, 457, 459, 461, 463, 465, 467, 469, 476, 480, 491, 492, 493,498, 510A, 511A, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 758, 759, 866, and 1009 received in evidence)

MS. LORING: Then we have for identification only demonstratives Plaintiff's Exhibits 510, 511, 1010, 1011, and 1012.

THE COURT: I am not admitting those. I will just see them and utilize them as demonstratives.

Is Mr. Oshlack here? Come forward, sir.

(Continued on next page)

BENJAMIN OSHLACK,

called as a witness by the plaintiff,

having been duly sworn, testified as follows:

THE COURT: Welcome back, sir.

Your witness.

MS. LORING: Your Honor, perhaps if I could put some of those away, because we have others. There are five volumes, but we're really only going to be using, I think, three.

DIRECT EXAMINATION

BY MS. LORING:

Q. Please state your name.

A. Benjamin Oshlack.

Q. For whom do you work?

A. Purdue.

Q. How long have you been employed by Purdue?

A. Approximately 23 years.

Q. What is your job title?

A. Vice president pharmaceutics.

Q. How long have you held that position?

A. For approximately four years.

Q. Are you associated with the patents in suit?

A. Yes.

Q. What is your association?

A. I'm one of the named inventors.

Q. Where were you born, Mr. Oshlack?

A. Melbourne, Australia.

Q. Where did you go to college?

A. In Melbourne, Australia.

Q. What was your major?

A. Pharmacy.

Q. Why did you major in pharmacy?

A. I enjoyed the sciences, and at that time I wanted to go into retail pharmacy.

Q. When did you graduate?

A. 1972.

Q. Did you stay in Australia at the college?

A. After, shortly after I graduated, I traveled overseas and I traveled first to Israel, and I was there for approximately two years. After that I traveled to the U.K., where I worked for approximately six months. And then I went to Holland, where I was for four years before coming to the United States.

Q. What did you do in the pharmaceutical industry while you were in Holland?

A. In Holland, I worked in the pharmaceutical industry in the area of pharmaceutical development.

Q. For whom did you work?

A. I worked for a company called Dagra.

Q. What type of products did you work on while at Dagra?

A. I worked on immediate-release tablets, mostly in the area of vitamins.

A. I recall these discussions, yes.

Q. Could you please explain what your understanding is of what occurred.

A. Well, as I recall, there was discussions about the in vivo peak of the C max, of the test material. And there was a lot of discussion whether we thought that it should be further blunted. And there were some discussions about reformulation of that.

And I do recall that we decided to do a little further testing before we got back and reformulated.

Q. Did you ever reformulate?

A. As it turned out we did not reformulate.

THE COURT: Just a moment. You never reformulated for what tablet, sir?

THE WITNESS: OxyContin.

THE COURT: You mean the first combination that you hit upon of mix of excipients and active ingredient was the one that you stayed with throughout?

THE WITNESS: The first one that we -- um, no. Actually, the -- I don't -- the first one that we tested actually did not become the final product. No, it did not. It did not become the marketed product.

Q. Did there come a time when you began working on a controlled-release codeine formulation?

A. Yes.

Q. When did you conduct that work?
A. In the early 1980's.
Q. What controlled-release system did you use?
A. I used the Contin system, which was the system that was developed at Napp in the U.K.
Q. What did you first do to attempt to develop a controlled-release codeine formulation?
A. What I did is, I attempted to develop a codeine formulation using the commonly used salt of codeine and putting it into the Contin system, and those attempts to produce a controlled-release were not successful.
Q. I would like you to look, please, at Plaintiff's Exhibit 498 in your witness book.

Do you recognize this document?

A. Yes.
Q. What is it?
A. This is a memo that I wrote to Dr. Krisnamurthy, who is my counterpart in the Canadian company. It's a memo on the development and history of codeine Contin.
Q. Could you look, please -- why did you prepare this memo?
A. This memo was -- this report was prepared for submission to -- as part of the submission to the health authorities in Canada.
Q. Look, please, at page P 569554.
A. Yes.

Q. I would like you to focus on the second paragraph and the second sentence. It says, "It was decided to use the patented Contin system as the mechanism for the controlled-release delivery."

And now I'd like you to look at the third paragraph, please. It says, "An initial tablet formula was developed using quantities of cellulose and higher aliphatic alcohol that have been seen to be effective in retarding some other drug molecules in matrix tablets." The reference there to cellulose and higher aliphatic alcohol, what is that a reference to?

A. That's a reference to the two retardants that I used in the Contin matrix, and those are the retardants that are in the Contin system.

Q. What other drug molecules were you referring to there?

A. The other drug molecules that were used in the Contin system were aminophylline at the time. I think there was morphine at the time. And theophylline.

Q. Turn, please, to page P 569555. And look, please, at the table there in the middle. You testified earlier that the codeine salt in a Contin system was unsuccessful. How did you know it was unsuccessful?

A. Well, the dissolution -- the dissolution was very fast. You had 82 percent out in two hours and 100 percent out in four hours, so that looked like it would be too fast for further testing.

Q. Too fast for what?
A. For twice-a-day administration.
Q. Now look at the paragraph under the table.
Can you explain why you thought that 100 percent out in four hours would be too fast?
A. It's hard to know -- it's hard to know exactly where -- what you would want to test. You can have two extremes. If you have something that dissolves immediately upon ingestion, you think that would be too fast. If you have something that's like a brick in a dissolution bath and doesn't come out at all, you'd say that would be too slow. This seemed, for a twice-a-day administration, this seemed a little fast, especially having so much out in the first two, three hours.
Q. After you found that the salt in the Contin system was unsuccessful, what did you do, if anything, to try to slow down the dissolution?
A. Well, since I was -- did -- had no success in using the commonly used salts in the Contin system, what I decided to do is see if I would have more success by using the less soluble free base.
Q. And was that successful?
A. That was also not successful, by itself.
Q. Were you ultimately able to formulate a controlled-release codeine tablet for twice-a-day administration?
A. Eventually, after considerable work, I was able to develop

a controlled-release codeine product, by combining the free salt -- the salt with the free base, within the Contin system.

Q. How did you know that was ultimately successful?

A. It was tested in humans, and it was eventually developed.

Q. Did you receive a patent for your codeine salt based combination?

A. Yes, I did.

Q. I would like you to look at Plaintiff's Exhibit 14, which is U.S. Patent 4,443,428. Is this a copy of the patent you received?

A. Yes.

THE COURT: Why don't you find a logical point to break. I don't know how long you were going to spend with this patent, but it's up to you.

MS. LORING: I'm done with the patent, your Honor.

THE COURT: All right. Fine. Then is this a logical point to break?

MS. LORING: Yes, it is. Yes.

THE COURT: All right. Thank you. It's ten after 4. Let's pick up again at 9:30 on Monday, and essentially you'll have the whole day on Monday.

All right. Thank you. I'll see you all on Monday.

(Witness excused)

(Adjourned to 9:30 a.m., June 9, 2003)

(Trial resumed)

THE COURT: Let's proceed. Let's have Mr. Oshlack take the stand again.

BENJAMIN OSHLACK, resumed.

THE COURT: Mr. Oshlack, you remain under oath. I take it you understand that?

THE WITNESS: Yes, your Honor.

THE COURT: Proceed.

MS. LORING: Good morning, your Honor.

DIRECT EXAMINATION (continued)

BY MS. LORING:

Q. Good morning, Mr. Oshlack. Mr. Oshlack, on Wednesday you testified about the iterative process in drug development and you provided an example of how that process occurred during the development of OxyContin. Do you recall your testimony about discussions whether to reformulate controlled-release oxycodone to provide a more blunt Cmax?

A. Yes.

Q. I asked you whether you had reformulated controlled-release oxycodone, and you said no. Do you recall that?

A. I recall, yes.

Q. When you said no, did you mean that you never reformulated controlled-release oxycodone for any purpose or that you never reformulated for the purpose of blunting the Cmax?

A. We never reformulated for the purpose of further blunting

the Cmax.

Q. What do you mean by the phrase "blunting the Cmax"?

A. The Cmax is the peak height of the blood levels obtained after administration of the drug. So blunting discussions mean that the peak height should in fact be a little lower, blunting would make it lower. What we ended up with is that we didn't reformulate in reference to blunting the Cmax.

THE COURT: Again, blunting Cmax means lowering the concentration of the maximum amount of drug or lowering the concentration of the drug at its highest point?

THE WITNESS: That's correct.

THE COURT: All right.

Q. When did you begin your work in the development of OxyContin?

A. I'm sorry. I didn't hear the question.

Q. When did you begin your work in the development of OxyContin?

A. In late 1985, shortly after Bob Kaiko joined Purdue.

Q. What led you to begin this development work?

A. After Bob Kaiko joined Purdue, he championed the concept of a twice a day oxycodone, and then it became a very active project.

Q. I would like you to look, please, at your laboratory notebook binder. That should be right on the shelf there. Tell me, please, what these exhibits are.

A. These are comments of my lab notebooks that I used in product development.

Q. Why do you keep lab notebooks?

A. Lab notebooks are kept as a record of the laboratory activities that are done in the lab, and that is the official record of the work done.

Q. Who made the entries in the notebooks?

A. It was either myself or staff reporting to me.

Q. Do these notebooks record experiments conducted on controlled-release oxycodone?

A. That's correct.

Q. I would like you to look now at Plaintiff's Exhibit 511A, which is a separate binder. Please take a look at this and tell me what it is.

A. These are copies of the relevant pages of the notebooks that record the development work relating to the development of OxyContin.

Q. The notebook has numbered tabs in it. Could you please describe how the notebook is organized, what is behind each tab.

A. The tab numbers basically represent a particular experiment and the results of that experiment.

Q. How did you begin your work in the development of OxyContin?

A. We began our work in the development of OxyContin at the

end of '85, looking to see if we can match the dissolution target of MS Contin.

Q. Did you use any particular controlled-release matrix?

A. We began by looking at the Contin matrix.

Q. Why did you look at the Contin matrix initially?

A. We looked at the Contin matrix because that was the matrix that we had a lot of experience with. It was a patented matrix that we had, and that was the reason I looked at it first.

Q. Look, please, at tab 10 of Plaintiff's Exhibit 511A. I would like you to focus on the first page.

A. Yes.

Q. Was this experiment part of your attempt to formulate controlled-release oxycodone using the Contin system?

A. Yes.

Q. What is shown on this page?

A. What is shown on this page is the ingredients of the formulation, in particular the granulation, and also the procedure, just a brief summary of the procedure used to manufacture the granulation.

Q. Up at the top there is a book number. What does that refer to?

A. That book number is in this case 636, and that refers to the notebook number. So every notebook that was issued received a number, and this was the 636th notebook.

Q. Then there is a number in the upper right-hand corner 43.

What is that?

A. That number is the 43rd page of the notebook of 636. And generally most notebooks had 50 pages.

Q. Turn the page, please, to page 44 of notebook 636. I would like you to look under "Objective" and tell me what this page relates to.

A. This page relates to the tableting of the granulation that was prepared on the previous page, on page 43, the formulation for the tableting and the procedure, and some noting of the results.

Q. Was there a particular nomenclature used at Purdue to refer to specific experimental formulations?

A. There was. The notebook number and the page number eventually became the descriptive of the batch that was made. So in this case, if you are looking at page 44, the kind of tablets that were made ended up becoming referred to as lot 636-44. So we used that nomenclature in fact to identify the lot that was made.

Q. Look at the next page, please, 636, notebook page 45.

A. Yes.

Q. At the top there is an entry "Purpose." Tell us what is shown on this page.

A. On this page what is done is the dissolution is performed of the tablets that were made on the previous page.

Q. Looking further down the page there is a table.

11, tab 12, tab 13, tab 16, and tab 21.

Q. Generally, in these experiments what form of oxycodone did you use?

A. Oxycodone hydrochloride, which is the salt form.

Q. Generally, what were the results of these experiments in terms of dissolution?

A. Generally, the dissolution data was too fast.

Q. Would you look, please, at entry number 16 on page 6. Tell us what experiment is summarized here.

A. This is an experiment. The experiment summarized here shows that a Contin tablet was made by mixing, using 50 percent of the active substance as the hydrochloride or the salt form and 50 percent of the active substance being represented by the free base.

Q. Why did you conduct this experiment?

A. Since I was having difficulty retarding the oxycodone hydrochloride within the Contin system, I thought that I would look at substituting some of that with the less soluble base form. I had some experience earlier with codeine, not being able to retard codeine with salt in the Contin system. And doing this, by replacing some of it with a less soluble form of the codeine, I was able to retard within the Contin system.

THE COURT: What does it mean to say within the Contin system?

THE WITNESS: What that means is the Contin system

gives you a guide of what returns to use. The returns in the Contin system are a higher aliphatic alcohol and a cellulose polymer. So you use those retardants, put your drug into it, into a matrix of those retardants, and you hope that it will retard adequately after you tested the tablet.

Q. What were the results when you attempted using 50 percent oxycodone salt and 50 percent oxycodone base?

A. Even using the less soluble base, dissolution still was not successful. It was still too fast.

Q. Did there come a time when you attempted to use different retardants in your controlled-release oxycodone formulations?

A. Yes.

Q. What different retardants did you use?

A. I also looked at using the acrylic resins in combination with higher aliphatic alcohol.

Q. What are acrylic resins?

A. Acrylic resins are, in essence, Plexiglas.

Q. What brand of acrylic resins did you use in your experiments?

A. I used eudragit.

Q. Why did you decide to use eudragit in your formulations?

A. I knew they were very effective retardants, so I thought that that may help in this effort.

Q. Did you have any prior experience using eudrigat in a controlled-release matrix?

A. I had some prior experience of using eudrigat in such a matrix.

Q. Did that matrix have a name within Purdue?

A. Yes. The matrix was called the Acrocontin matrix or the Acrocontin system.

Q. I would like you to look now at entry 15 of Exhibit 511, the same page we were on before. What formulation is shown there?

A. The formulation shown here is lot 855-07.

Q. What were the results of the dissolution test for this formulation?

A. The results of this dissolution test, as far as dissolution only goes, looked promising when compared to MS Contin, looked promising for further development.

Q. What did you mean by "promising" in that context?

A. What I meant by "promising" is I'm talking about dissolution only, and promising for further development.

Q. Was the 855-07 formulation ever tested in clinical studies?

A. No.

Q. Why not?

A. It couldn't be, because it was never made as a clinical batch according to GMP, which means good manufacturing practices. So I would never be able to use 855-07 in the main because it would have been illegal to do that.

Q. Did you ever attempt to make a clinical batch using the

855-07 formulation?

A. Yes, I did.

Q. What was the result?

A. The results were I was unable to successfully make a clinical batch of 855-07.

Q. When you attempted to make the clinical batches, was it the same scale as 855-07 or a different scale?

A. I also at the same time attempted to scale up 855-07 so that I could determine if it is a feasible formulation. You also needed a certain quantity, a decent amount of quantity of tablets when you make a clinical batch.

Q. Look, please, at entries 27, 28, 29, and then 35 of Exhibit 511. Are these the scale-up clinical batches you just referred to?

A. 27, 28, 29 -- what was the last one? I'm sorry.

Q. 35.

A. Yes. Those were my attempts to make a clinical batch of 855-07.

Q. Look, please, back at entry 15 on page 6 of 511 and tell us what solvent you used in making the 855-07 tablets.

A. The solvent that I used in making 855-07 was a blend of IPA or isopropyl alcohol with acetone.

Q. What is the function of a solvent?

A. The function of the solvent is to activate the binder and activate retardant and bind them together with the diluent in

the drug.

Q. IPA acetone, is that organic or aqueous?

A. That is organic.

Q. Why did you use an organic solvent?

A. We started off by using the organic solvent because that would probably be the most effective way to activate the retardant.

Q. Where you satisfied with the use of the IPA acetone solvent?

A. No, not at all.

Q. Why not?

A. A couple of reasons. Firstly, the use of IPA and acetone as a solvent is very explosive. The IPA acetone solvent has a very high flash point, which would make it very explosive and very dangerous for the workers and the operators making the batches, making the formulations. The second issue is that there are environmental requirements, environmental restrictions on using such solvents.

Q. To your knowledge, were the problems with organic solvents that you just discussed commonly known in the pharmaceutical industry?

A. Yes, they were.

Q. Did you try to make a 10-milligram formulation that did not use IPA acetone as a solvent?

A. Yes.

Q. What did you attempt to do?

A. I attempted to reduce the explosivity of the sulfur used, and eventually I was able to do that by using a combination of ethanol and water.

Q. Are you done?

A. Yes. Using ethanol and water, yes.

Q. Look, please, at entry 48 in Exhibit 511, which is on page 16. Please tell the Court what experiment is summarized here.

A. Entry 48 describes experiment lot CB 1523, which was prepared as a clinical batch. "CB" is the nomenclature that we use to identify a clinical batch. The solvent used was a blend of ethanol, which is alcohol and water.

Q. What did you conclude about the in vitro dissolution results of tests performed on CB 1523?

A. The in vitro dissolution 1523 looked promising for further development and matched the MS Contin quite nicely.

Q. Is the formulation of CD 1523 disclosed in the '912 patent?

A. Yes, it is. It is example 2.

Q. Did you continue your efforts to design a 10-milligram tablet that used water as a solvent?

A. Yes.

Q. I would like you to turn, please, to page 18 of Exhibit 511 and look at entry 59. What formulations are recorded here?

A. This is clinical batch lot 1838, and this clinical batch and this formulation used only water. It was totally aqueous,

the manufacturing was totally aqueous, and this formulation ended up becoming the final formulation of the OxyContin product for the 10-milligram.

Q. Is the formulation for CD 1838 disclosed in the '912 patent?

A. Yes, it is. It is example 3.

Q. Now turn, please, to entry 60 on page 19 of Exhibit 511. What formulation is summarized here?

A. This is a formulation clinical batch lot CB 2112. This is exactly the same formulation as the earlier one, CB 1838. However, this was the first production-scale, full-production-scale batch that was made in the manufacturing facility, and it was made at 137-kilo scale as opposed to the earlier batch, which was made at I think around 5 kilos.

Q. This is also the formulation for OxyContin?

A. Yes, it is also the formulation for the marketed product.

Q. Did you ever develop a 30-milligram controlled-release oxycodone formulation?

A. Yes.

Q. Please look at entry 33 on page 11 of Exhibit 511. Tell us what formulation is summarized here.

A. This is clinical batch CB lot 1441, and this is a 30-milligram batch made in a total aqueous media.

Q. What was the results of dissolution testing on this batch?

A. The results of this looked promising for further testing.

THE COURT: Mr. Oshlack, had you had experience with MS Contin by 1985?

THE WITNESS: MS Contin came onto the market in the U.S. in I think around 1984.

THE COURT: So that was an already-existing product?

THE WITNESS: Yes.

THE COURT: I don't know if this is technically possible. Was any thought given to simply replacing the active ingredient in MS Contin, morphine, with the active ingredient in what ultimately became OxyContin, that is, oxycodone?

Let me ask it more simply. Can you just take the morphine out of MS Contin and plug in oxycodone?

THE WITNESS: That's where we started, and we weren't successful.

THE COURT: Is that shown in 511? When you say that is where we started, is that one of the examples in the 511 summary?

THE WITNESS: In PX --

THE COURT: PX-511.

THE WITNESS: Yes, it is.

THE COURT: Which one is that? You are saying that was your starting point because you had had a successful product?

THE WITNESS: Right.

THE COURT: So you used that as a starting point to

see if you could have an oxycodone product.

THE WITNESS: I believe that it is tab 10. Look at tab 10.

THE COURT: Yes.

THE WITNESS: I believe that is where I plugged in the exact formulation.

THE COURT: This is your MS Contin formulation but just plugging in oxycodone in place of morphine?

THE WITNESS: Right, I think so. I would have to check it side-by-side, but I think so.

THE COURT: With magnesium stearate and talc as the lubricant?

THE WITNESS: Yes.

THE COURT: You found that the dissolution rate was too fast?

THE WITNESS: Yes.

THE COURT: All right. Thank you.

Q. Let's go back to CD 1441 and look at page 11, entry 33. Was that formulation ever tested in clinical studies?

A. Yes.

Q. What use was made of the formulation ultimately?

A. It was used in the clinical study, but the product was never commercialized.

Q. Do you have an understanding of why it was never commercialized?

A. As far as I remember, I believe that originally the medical department were thinking that we would start off with a 10 and do a dosage range in increments of 3. So it would go 10, 30, 90. But then I think the medical department realized that increments of 2 would be the way to go. What we ended up going with is increments of 2. So we ended up going with 10, 20, 40, 80, and eventually 160.

Q. Is the formulation CB 1441 disclosed in the '912 patent?

A. Example 1 of the '912 patent.

Q. Look now, please, at page 24 of Exhibit 511, entry 84. I believe it is the last entry in the exhibit. What formulation is summarized here?

A. This is CB Y-8, which is the first scale-up batch of the 20-milligram dosage form, which became the 20-milligram marketed OxyContin product.

Q. Tell us, please, what is shown in entry 83.

A. Entry 83 is a small lab batch of the same formulation of the 20-milligram tablet that was made in the lab.

Q. Is the formulation for CB Y-8 disclosed in the '912 patent?

A. Yes, it is. It is example 4.

Q. Have you prepared an exhibit summarizing the formulations disclosed in the examples of the patents in suit?

A. Yes, I have.

Q. Look, please, at Plaintiff's Exhibit 1009 and tell us whether this is the exhibit you prepared.

A. Yes, it is.

Q. What is shown in this exhibit?

A. What is shown in this exhibit is the formulation of the particular batch. The next column shows the description, which is basically describing the strength of the tablet and whether the granulation -- whether the manufacture was organic or aqueous. The next column shows the corresponding example numbers in the '912 patent. And the last column shows the corresponding number, example numbers, in the '331 patent.

Q. Did you report the results of the CR oxycodone formulation that is we have just been discussing to others at Purdue?

A. Yes, I did. I reported the results with my boss, my colleagues in the lab, my international colleagues, and also particularly I discussed them with my colleagues in the medical department and in particular Bob Kaiko.

Q. Did Dr. Kaiko participate in the decisions as to whether particular formulations should be tested in clinical studies?

A. Yes, he did.

Q. Did you prepare any reports recording the history of the development of OxyContin?

A. Yes, I did.

Q. What were those reports referred to as?

A. Development reports.

Q. Please explain what development reports are.

A. Development reports are a summary of the history of the

development of the product, and they are used for purposes for the FDA and they are used in NDA submissions, new drug applications.

Q. I would like you to look in your witness book at Plaintiff's Exhibit 491, and tell us what this document is.

A. This is a development report summarizing the development history of the OxyContin 10-milligram tablet.

Q. Do you see a signature on the first page?

A. Yes.

Q. What is the significance of your signature?

A. That signature refers to my approval of this report.

Q. When you approved the report, did you ensure that it was accurate?

A. Yes.

Q. I would like you to look now at Plaintiff's Exhibit 492. Tell us what this document is.

A. This is a summary of the development report of the OxyContin 20-milligram tablet.

Q. Does your signature appear in the "approved by" line on the document as well?

A. Yes.

Q. Did you ensure that this document was accurate before you approved it?

A. Yes.

Q. Now I would like you to look, please, at Exhibit 493. What

Exhibit 510-A is.

A. 510-A are copies of the relevant notebook pages that record the work that was done at that period of time.

Q. Have you prepared a summary chart describing the work contained in Exhibit 510-A?

A. Yes.

Q. I would like you to look, please, at Exhibit 510, which is in your witness book, and tell us whether that is the summary chart that you prepared.

A. Yes.

Q. Is the format of Exhibit 510 the same as that of Exhibit 511 that we were discussing earlier?

A. Yes, it is.

Q. And do you believe that Exhibit 510 accurately reflects your early work with controlled-release oxycodone?

A. Yes.

Q. Do the entries in Exhibit 510 correspond to the tabs in Exhibit 510-A?

A. Yes.

Q. I would like you to look, please, at Exhibit 510 and tell us which entries summarize your work with oxycodone in the Contin system.

A. Entry 1 and tab 1, tab 2, tab 3, tab 4, tab 5, tab 6, tab 7, tab 8.

Q. Did you tell anyone at Napp Pharmaceuticals about your

efforts at this time to prepare controlled-release oxycodone in the Contin system?

A. Yes, I did.

Q. Please explain to the Court what Napp Pharmaceuticals was.

A. Napp Pharmaceuticals was our associated company in the United Kingdom.

Q. Look, please, at Plaintiff's Exhibit 476 and tell us what that is, in your witness book.

A. This is a memorandum from myself to Mr. Stewart Leslie.

Q. When did you prepare this memo?

A. August the 5th, 1983.

Q. Who was Mr. Leslie at that time?

A. Mr. Leslie was my counterpart in the British company. And he was also the inventor of the Contin system.

Q. Look at the first page under the heading "Oxycodone in the Contin System." What did you tell Mr. Leslie about the dissolution of your initial oxycodone Contin formulations?

A. I told him that we put oxycodone into the -- oxycodone base into the Contin system and the dissolution was too fast. We had 100 percent dissolved in two hours.

Q. Look at the next, the second paragraph under that heading. It starts with "many trials." What did you tell Mr. Leslie about your later experiments using the Contin system?

A. Well, what I was telling him was that I was increasing the retardants that are specified within the Contin system, which

is the cellulose and the high aliphatic alcohol, the wax -- that's that waxy -- and still were not able to get any retardation.

Q. Now I would like you to look at the last paragraph of this section, that starts with "at this very time." It says, "Experimentation is being conducted using the acrylic resins. It appears that controlled-release may be able to be achieved using this material." Acrylic resins is a reference to what?

A. Eudragit.

Q. As of the date of this memorandum, had you obtained a controlled release oxycodone Contin formulation that was suitable for twice-a-day administration?

A. No.

Q. I would like you to look again, please, at Exhibit 510.

THE COURT: Before you go to that, 476, again, you're using the phrase "in the Contin system." You see "oxycodone in the Contin system." And in 2 it says "in the Contin system." Tell me again what the Contin system is.

THE WITNESS: OK. If you look, the Contin system described the use of a combination of two retardants. And the retardants cited in the Contin system are a cellulose polymer and a higher aliphatic alcohol. And the cellulose polymer are products like methylcel or hydroxyethyl cellulose, and the higher aliphatic alcohol are things like stearyl alcohol or cetostearyl alcohol, and they look like waxes, like solid

A. What is meant here is that, as I said, it's a -- your dissolution is a qualitative indication of what you think this experimental formulation would be, and based on that qualitative information, you would then use that as what you think would be a potential candidate for testing in man, and that's basically what I think you can get out of this.

Q. I would like you to turn now to the '912 patent in suit, which is Plaintiff's Exhibit 8. Do you recognize this?

A. What exhibit was it?

THE COURT: 8.

Q. 8, sorry, in your witness book.

A. Yes.

Q. Do you recognize the '912 patent?

A. Yes, I do.

Q. And you are named as an inventor?

A. Yes.

Q. Please describe your contribution to the inventions disclosed in the '912 patent.

A. I provided the formulation examples and also provided the in vitro dissolution data.

Q. John Minogue is also listed as an inventor. Who is John Minogue?

A. John Minogue is a gentleman that reported to me.

Q. What was your understanding of Mr. Minogue's contribution to the inventions disclosed in the patents in suit?

A. Mr. Minogue and myself worked together, and he also did some of the examples of the work together, and he contributed in the same way.

Q. I would like you to look, please, at column 12, starting at column 12, examples 7 through 12. Please explain what these are.

A. These are examples of oxycodone. Most of them are oxycodone in the Contin system. And the last two examples are a combination system.

Q. When did you prepare these formulations?

A. In 1991.

Q. Why did you prepare them?

A. I prepared them, they were -- there were some similar examples that were made for hydromorphone, and so I prepared them putting oxycodone into it, and I wanted to see how oxycodone would perform in those particular formulations of oxycodone hydrochloride.

Q. Were these formulations ever tested in humans?

A. No, they weren't.

Q. Were these the first oxycodone formulations using the Contin system that gave you promising in vitro dissolution results?

A. Surprisingly, yes.

Q. Do you have an understanding of why these results were promising?

A. I can't be sure. I don't know.

Q. Did there come a time when you assigned your rights to the three patents in suit?

A. Yes.

Q. I would like you to look at Plaintiff's Exhibit 759, and tell me whether you recognize this document.

A. This is assignment of the patent to Euroceltique.

Q. Is this your signature at the bottom of the page?

A. Yes, it is.

Q. Is this an assignment of all of your rights to the three patents in suit?

A. Yes.

Q. I would like you to turn now to Plaintiff's Exhibit 12, which is U.S. Patent 5,266,331. Do you recognize this patent?

A. I'm sorry? Beg pardon?

Q. Do you recognize this patent?

A. Yes.

Q. Are you a named inventor?

A. Yes.

Q. What was your contribution to this patent?

A. My contributions to this patent were the formulation, examples of the formulations in the in vitro dissolution data.

Q. To your knowledge, who was responsible for the clinical studies disclosed in your previous patent?

A. Bob Kaiko.

AFTERNOON SESSION

2:15 p.m.

BENJAMIN OSHLACK, Resumed.

THE COURT: We can continue.

MR. FILARDI: Good afternoon, your Honor.

CROSS EXAMINATION (Cont'd)

BY MR. FILARDI:

Q. Good afternoon, Mr. Oshlack. During your direct examination by your counsel, you went through, in essence, the history of how you came to prepare certain formulations, including oxycodone, and their dissolution profiles. Do you recall that?

A. Yes.

Q. You set them forth in Exhibits -- the work that you did in Exhibits 510, 511, summarized in 510-A and 511-A.

I think it's the other way around. 510, 511-A, those are the actual records, and the summaries you filed, 510, 511. Isn't that true?

THE COURT: You don't have to worry about which is the summaries and which is the --

THE WITNESS: Yes.

THE COURT: One set are the summaries and the other set is the actual lab notes. Do you remember, you were shown those?

THE WITNESS: Yes, I remember.

Q. During the course of that work, you were aware of MS Contin; isn't that correct?

A. In what sense?

THE COURT: I think you told me earlier that you started off by plugging in OxyContin in lieu of morphine in the MS Contin formulation to see if that worked.

THE WITNESS: Right. I believe that was in 1985.

THE COURT: But you knew MS Contin was out there and a viable product and was one means of having an opioid analgesic on timed release.

THE WITNESS: Yes.

THE COURT: All right. Proceed.

Q. And you knew that MS Contin was a twice-a-day, 12-hour drug.

A. Yes.

Q. And you knew that it had a 2- to 4-hour T max.

A. I'm not sure that I knew that exactly.

Q. You don't recall that being published by at least the mid 1980's in the United States by Purdue?

A. I don't know.

Q. But surely you knew that MS Contin was a drug for moderate to severe pain.

A. Yes.

Q. Now, putting aside when this all occurred, would I be correct in stating that it was important for Purdue, you and

your coworkers, to mimic the profile, the dissolution profile, of MS Contin as a starting point for your oxycodone project?

A. Right. This was the -- as I said earlier, this was the starting point.

THE COURT: You wanted to, as I recall your testimony, sir, your aim was to replicate the dissolution profile of MS Contin.

THE WITNESS: Right.

Q. And the reason you did that is because that was done in a reasonable expectation that with that dissolution profile matched to MS Contin you would also have a 12-hour drug, twice-a-day drug; isn't that correct? A reasonable expectation.

A. I would assume so.

Q. Now, let's get to when this started. Are you aware that Dr. Kaiko testified before you in this case?

A. Yes.

Q. Did you have an opportunity to read his testimony?

A. No.

Q. I'm going to tell you that in his testimony, he was asked the following question and gave the following answer:

"Q. Sir, you only realized today that in fact Oshlack and his coworkers had already started, for example, to mimic MS Contin, its profile, before you came to Purdue; isn't that correct?

"A. No. I had no reason to believe that they ever tried to

mimic MS Contin before I arrived at Purdue."

My question is, is that your recollection as to what occurred at the time that Kaiko came to your company?

MS. LORING: Your Honor --

THE COURT: Sustained.

MS. LORING: I object to the testimony in that way because I think it takes the testimony out of context and ignores subsequent testimony by Dr. Kaiko.

THE COURT: All right. I was sustaining it for a different reason, but it's sustained.

MR. FILARDI: I'll move on.

Q. In your testimony today, I believe you said that the OxyContin work began in 1985, roughly, after Dr. Kaiko came to the company. Is that correct?

A. Correct.

Q. And was that, in 1985, that's the date you recollect you first substituted oxycodone for morphine in the Contin system. Is that correct?

A. I don't remember exactly when I substituted, milligram for milligram, the oxycodone for morphine, with the exact formulation of the Contin system. I believe it was in late '85, but I can't be a hundred percent sure with the exact formulations.

Q. It was your further testimony that in that 1985 period, that's when the whole project started, because Robert Kaiko

THE COURT: The claim here is that vis-a-vis the class of opioid and analgesics, OxyContin was relatively easy to titrate?

THE WITNESS: Yes, sir.

THE COURT: Thank you. That is helpful.

MR. FILARDI: Your Honor, could I ask that we take an afternoon break before I begin?

THE COURT: Yes, of course. Let's take a short break. Thank you.

(Recess)

MR. SCHWARTZ: I have a brief offer of exhibits which there are no objections to, which are PTX-381, 484, PTX-722A, PTX-908, PTX-909, PTX-727A, 717A, and 475A.

THE COURT: Admitted.

(Plaintiff's Exhibits 381, 475A, 484, 717A, 722A, 727A, 908, and 909 received in evidence)

CROSS-EXAMINATION

BY MR. FILARDI:

Q. Good afternoon, Dr. Goldenheim.

A. Good afternoon.

Q. You mentioned 1985 as the date when Dr. Kaiko first joined Purdue, do you recall that?

A. Yes.

Q. Do you recall you also said that you discussed with him or he mentioned the advantages of oxycodone?

A. Yes.
Q. Do I understand correctly that from the very outset of Dr. Kaiko's arrival at Purdue, he, quote-unquote, championed the concept of a controlled-release oxycodone formulation?
A. Yes.
Q. Have you heard anything about Dr. Kaiko's insight that a controlled-release oxycodone formulation would have a reduced dosage range leading to quicker titration? Have you ever heard that?
A. Yes.
Q. Was that one of the advantages that Dr. Kaiko mentioned to you at that early date?
A. I don't recall.
Q. Do you recall when he first told you about this insight or institution he had about controlled-release oxycodone?
A. I'm sorry. Could you repeat the question.
Q. Yes. Do you recall when you first heard from Dr. Kaiko about his insight or institution that with a controlled-release oxycodone you might be able to obtain the advantage of reduced dosage range leading to quicker titration?
A. I don't recall the first time, no.
Q. Just as a frame of reference, you mentioned the studies that were done here in some of these exhibits. Was it before the clinical work that was being done on the formulations of Oshlack?

A. Which clinical work?
Q. Say the initial clinical work, steady-state work, on Oshlack's formulations, the oxycodone Acrocontin formulations.
A. I have no recollection of any such conversations at that time, no.
Q. Let me turn you first, then, to Plaintiff's Exhibit 31, which is your background and outline. Could you please take that in hand. There came a time, it appears roughly in 1988, when you became the vice president of scientific and medical affairs and kept that title through, it appears, 2000, although you were group vice president and executive vice president. But that title scientific and medical affairs is there. Do you see that?
A. Yes.
Q. In connection with your work, did you keep yourself up to date on the development of the controlled-release oxycodone formulation by Purdue which later became OxyContin?
A. Yes.
Q. Were you aware of what was going on in terms of IND's submitted? I think the IND was submitted roughly in 1986. Do you recall that?
A. I certainly was aware that an IND was submitted. That sounds like the right date.
Q. Sounds like the right frame. Now, did you have some general understanding on an ongoing basis of what your company

and that you have reviewed them. Did you arrive at an opinion on what the claims meant?

MR. FLATTMANN: Objection, your Honor.

Q. Or did you arrive at an understanding of the claims?

A. I believe so.

Q. Could you tell us what that is?

MR. FLATTMANN: I am sorry, your Honor. I have to press the objection. He testified he hadn't formed a claim construction and he simply adopted Purdue's. He testified that he didn't form a claim construction but that, rather, he adopted Purdue's. That's in his expert report, I believe, at paragraph 43.

THE COURT: Sir.

MR. FLATTMANN: 32. I am sorry.

THE COURT: Let me take a look at it.

(Pause)

THE COURT: He says he has seen how Purdue construes the asserted claims. "I rely upon that construction herein." So his understanding is the same as Purdue's for these purposes, I take it.

MR. RHOADS: Yes.

THE COURT: Let's proceed. I will assume that that is the case.

BY MR. RHOADS:

Q. And how would you characterize Purdue's construction of the

claims, Dr. Mayersohn?

MR. FLATTMANN: Objection, your Honor. It is simply not a characterization in his report. He simply adopted it, your Honor.

THE COURT: I think that's right. Purdue has its construction -- well, no, that's all right. I will let him say what his understanding of Purdue's claim construction is. He says he is adopting Purdue's claim construction. I think I am entitled to know what he thinks that is.

Go ahead.

THE WITNESS: As I read claim one, it contains some information of a pharmacokinetic nature. It cites the mean maximum plasma concentration range resulting from different doses and it also cites a so-called Tmax, the time of occurrence of the maximum concentration, which is said to vary from 2 to 4.5 hours. There is also a corresponding average minimum concentration, which must arise from multiple dosing of steady-state ranges from 3 to about 30 nanograms per mil. For this range of doses it occurs between 12 to 14 hours, and there is a repeated administration -- excuse me, as a result of repeated administration every 12 hours.

What I take from this is an enormous range in plasma concentrations for oxycodone that go virtually from subtherapeutic to near toxic concentrations.

MR. FLATTMANN: Your Honor, move to strike everything

from "what I take from this is" as offering an opinion on a completely different issue on the scope of the claims and whether they are overbroad. That's not in his reports and it wasn't the question asked. It is nonresponsive.

MR. RHOADS: We are not --

THE COURT: I am not going to strike it. I understand the objection. Proceed.

THE WITNESS: The range that is cited here, as I indicated, is extremely wide and the analogy I can give to the court is one that occurred to me as I was passing a school yard --

THE COURT: I am sorry. I think that you have answered the question, is that not right? You answered the pending question, I believe.

THE WITNESS: I was just trying to make an analogy. That's fine, sir.

THE COURT: Next question.

BY MR. RHOADS:

Q. In your analysis, you did a number of calculations based on prior art and examined the claims and their scope, didn't you?

A. Yes.

Q. And could you tell us what you learned.

A. Well, again, basically this is the broad side of the barn. It is not possible to miss this concentration range no matter how this drug is dosed.

Steinberg & Raskin?

A. That's correct.

Q. That was your firm, basically, Steinberg & Raskin?

A. Yes.

Q. Eventually it became Steinberg Raskin Davidson?

A. That's correct.

Q. That is Mr. Clifford Davidson?

A. Yes.

Q. He is going to be testifying after you, are you aware of that?

A. I am aware, yes.

Q. In connection with your practice as a patent lawyer, am I correct that you are intimately familiar with the patent statute as it progressed over the course of your career?

A. I certainly was.

Q. Similarly with the code of practice and procedure in the code of federal regulations?

A. That's correct.

Q. Intimately familiar with those rules?

A. Yes, I was.

Q. As well as the MPEP, the Manual of Patent Examining Procedure?

A. Yes.

Q. Because your practice, would it be fair to say, focused in on the prosecution of patent applications?

A. That's correct.

Q. Before the United States patent office?

A. Yes.

Q. You were, during the course of your career, at least from roughly the 1977 time frame, familiar with Rule 56 and the duty of candor to the patent office?

A. I was.

Q. Were you here recently for the testimony of Mr. Bjorge, Gerald Bjorge?

A. I was sitting in back. Is that the man who testified just before me?

Q. Correct, sir.

A. Yes.

Q. Do I understand that you listened to his testimony?

A. Yes.

Q. Did you find anything unusual in what he said?

MR. GOLDMAN: Objection, your Honor.

THE COURT: Sustained as to form.

Q. Have you read rule 56?

A. A long time ago.

Q. Did you keep abreast of that rule and its changes as it developed, particularly during the period of 1991 to 1997?

A. Not to 1997.

Q. I'm sorry. To 1994.

A. 1994.

Q. And you practiced by it as a patent lawyer?

A. Pardon me?

Q. You practiced by that rule, observed that rule?

A. Yes, of course.

Q. You advised your clients on a regular basis about their duties under that rule?

A. Yes, I did.

Q. Aware of your duties under the rule?

A. Yes.

Q. You understand that the rule applies particularly to disclosure of relevant prior art?

A. Yes.

Q. It also applies to full disclosure of evidence to support facts presented to the patent office, isn't that correct?

A. Yes.

Q. As part of your practice, would I be correct to say that you understood at all times, at all relevant times, particularly in the period from 1991 to 1994, when you retired, that if any results were represented to the patent office as actual results, they had to be results that had actually been achieved?

A. If they were so represented.

Q. I would like to focus in for the moment on the period 1985 until you retired in 1994. In that period of time at your law firm, Purdue was a client?

A. I don't remember when they became a client, but during that time, yes.

Q. During that time 1985 until your retirement, would I be correct that you were the main attorney responsible at your firm for Purdue matters?

A. I was the senior attorney.

Q. There came a time in 1993 when Clifford Davidson took over as the senior attorney?

A. He took over the main prosecution of the cases on behalf of Purdue.

Q. When you say the main prosecution, did he become ultimately responsible for all the cases as of 1993?

A. I still supervised whenever possible. I can't answer that as a general statement.

Q. But certainly as of the time you left in 1994, was it with the understanding that with regard to the Purdue client the main attorney responsible was Clifford Davidson?

A. Yes.

Q. Do you know what the Controlled-Release Society is?

A. No.

Q. You are not a member of the Controlled-Release Society, would that be correct?

A. Correct.

Q. Am I correct that with regard to the Purdue client, they had internal patent meetings from time to time, R&P meetings?

A. Yes, they did.

Q. Did you ever attend any of those meetings in the period from 1991 until your retirement?

A. I remember attending meetings. As to when, I don't know.

Q. Do you recall that your firm represented Purdue in connection with what they called the controlled-release oxycodone project?

A. Yes, I do.

Q. Your firm, yourself and others, participated in assisting Purdue in the prosecution of its patent applications before the United States patent office relating to controlled-release oxycodone, isn't that correct?

A. Yes.

Q. Prior to the 1991 time frame, do you recall attending meetings where other controlled-release opioids other than oxycodone controlled-release were discussed?

A. No, I do not remember.

Q. Did you have any knowledge, at any time prior to your retirement, of information from Purdue relating to controlled-release codeine?

A. I don't remember.

Q. How about controlled-release hydromorphone?

A. I don't remember.

Q. How about controlled-release dihydrocodeine?

A. Do not remember.

Q. Controlled-release morphine?

A. Do not remember.

Q. Are you familiar with the patents that are the subject matter of this lawsuit, the patents to Kaiko, Oshlack, and others, the '912, the '042, and the '295?

A. No.

Q. Can we show the face of the '331 patent, Defendant's Exhibit 2044. I don't know if it is in your book. I am just going to ask you some background questions here. Can you see it on the screen before you?

A. Yes, I do.

Q. You are quite familiar with reading the title page of patents?

A. Yes, I am.

Q. And the information conveyed to the reader on these pages?

A. Yes.

Q. Let's see if we can have a framework here. Do you recall that you, sir, were personally involved in the prosecution of the patent applications of Purdue that led to the issuance of the '331 patent?

A. Yes, I was.

Q. You see here it says Euroceltique as the assignee?

A. Yes.

Q. Do you equate that for current purposes with Purdue?

A. Currently, yes.

Q. How about at the time this was filed, were they the same or separate entities, do you recall?

A. No.

Q. Benjamin Oshlack and Minogue and Mark Chasin, are those people that you met with? John Minogue.

A. I had met with Oshlack and I had met with Chasin. I do not ever remember meeting with Minogue.

Q. I'm sorry I mispronounced his name. The date of this patent is November 30, 1993?

A. Yes.

Q. That is prior to your retirement?

A. Yes.

Q. You see the patent was filed for on November 27, 1991?

A. Yes.

Q. It has a serial number, this information all being on the face of the patent?

A. Correct.

Q. It shows your firm as the agent or attorney?

A. Yes.

Q. It also shows two examiners, the primary examiner Thurman Page and the assistant examiner James Spear?

A. Yes.

Q. Do you recall dealing with James Spear, the assistant examiner, in terms of this application?

THE WITNESS: Yes, I do.

isn't that correct?

A. Correct.

Q. In the '331 it appeared as "oxycodone," as you intended?

A. Correct.

Q. The substance of this statement, it has the phrase it is usual in the pharmaceutical art to produce peak level at about Tmax 4 to 8. Do you understand that?

A. Yes.

Q. Let's go to the face of the '341, the face of this patent. Can we just take a look. It is the primary examiner, Thurman Page?

A. Yes.

Q. He was in fact the examiner that was in charge of this case?

A. Correct.

Q. James Spear wasn't attending here?

A. Yes.

Q. Do you recall that the '341 patent was referenced in the '331 application? In other words, it was mentioned there?

A. Yes.

Q. Would I be correct in stating that while it was mentioned, no mention was made of the portion of the '341 patent that called out a Tmax of 2 to 4?

A. Specifically calling, no. It was mentioned for the examiner to have in front of him.

Q. So it was mentioned and the examiner had it in front of him, but he would have to go find the Tmax of 2 to 4?

A. Yes.

Q. Now let's go to another reference. Your firm was involved in the '341, Steinberg & Raskin?

A. Correct.

Q. '341. Were you the principal attorney, main attorney responsible for the prosecution of that case?

A. Yes.

Q. Let's now go back in time a bit to Defendant's Exhibit 2047, the '984 patent, which I trust, your Honor, you have in your book. Again, I am just going to focus in on a small part of it.

Here again, this is the '984 patent, prosecuted by your firm?

A. Yes.

Q. Would you have been at this point in time, the filing would have been May of 1987, would you have been the principal attorney on behalf of your firm involved?

A. Yes.

Q. Again Thurman Page is the examiner here, the primary examiner?

A. Yes.

Q. James Spear was not involved in this case?

A. No.

Q. Let's go to the second page of this document. Do you recall, in column 2, lines 13 through 21, that this case pertains to dihydrocodeine?

A. Yes.

Q. Just to be clear, in the '331 case involved controlled-release oxycodone; the prior, '341, controlled-release hydromorphone; and this case now, the '984, pertained to controlled-release dihydrocodeine?

A. Yes.

Q. Would you agree with me that essentially this is the same paragraph, in essence, communicating to anyone who reads it that while it was usual in the prior art to have Tmax at 4 to 8, now we find Tmax 2 to 4 can be achieved?

MR. GOLDMAN: Objection as to form.

THE COURT: Sustained as to form.

Q. Would you agree with me that, in essence, we have the same language here as to dihydrocodeine as we saw in the '341 for hydromorphone and in the '331 for oxycodone?

A. Yes.

Q. Would I be correct in stating that at the point of time by 1992 -- I'm sorry -- 1991, November of 1991, the filing date of the '331, you had attended meetings where controlled-release dihydromorphone -- I'm sorry -- controlled-release hydromorphone, controlled-release dihydrocodeine, and controlled-release oxycodone had been discussed?

A. I do not remember.

Q. Could I have DDX-19, please. Let me see if I can explain this chart to you. Here is roughly the 1991-92 filing of the '331 and the '912 patents. Do you see that there?

A. Yes.

Q. This makes reference to the patents in suit as well as the '331. The '341 and the '909 Goldie patents, do you recall those had essentially the same disclosure?

A. Yes.

Q. They had the language that we have been speaking about, about the Tmax 2 to 4, correct?

A. Yes.

Q. Then we spoke about the '984 patent up here in 1989, and that had that same language as well, do you recall that?

A. Yes.

Q. Sitting here today, do you recall, at the time of the filing in 1991, had you met or had you been familiar with Dr. Kaiko from Purdue?

A. I do not remember.

Q. Do you have any recollection as to his writings with regard to controlled-release MS Contin?

A. No recollection.

Q. Do you have any recollection that at that time in 1991 you had seen any product brochures on MS Contin from your client Purdue?

A. I did not.
Q. You recollect that clearly?
A. Yes.
Q. Did you have any recollection that for MS Contin in fact the Tmax was between 2 and 4?
A. No recollection.
Q. Sitting here today, is it a surprise to you that in the prior art as of 1991 MS Contin was shown to have a Tmax of 2 to 4?
A. I just don't know.
Q. How about with regard to controlled-release codeine, do you recognize the phrase "codeine Contin" to be controlled-release codeine?
A. If you tell me. I do not know it.
Q. The Contin system is not familiar to you at Purdue?
A. No.
Q. How about the Acrocontin system?
A. Not familiar.
Q. With regard to controlled-release codeine Contin, whatever it is, did you have any understanding as of the filing date in 1991 for the '331 patent that the Purdue-published literature had set forth a Tmax for codeine Contin as between 2 and 4?
MR. GOLDMAN: Objection as to form.
THE COURT: I will allow it.
A. No recollection.

Q. Let's go now back, if I may, to the '331 disclosure. Let's go to the page 205585, please. It is Defendant's Exhibit 2008 at page 3 of the application, but it is EN205585.

Do you recall this language that was included? Apparently you took enough care at this point in the application to ensure that oxycodone was called out rather than hydromorphone. Do you see that?

A. Yes.

Q. Do you recall the origin of this language? Where did this language come from?

A. From the previous patent.

Q. Previous patents?

A. I only remember one. Only the hydromorphone is all I remember.

Q. Do you recall whether you selected this language together with Mr. Oshlack, one of the inventors?

A. I don't recall.

Q. How about Mr. Chasin or Mr. Minogue?

A. I have no specific recollection.

Q. Do you have any recollection, that prior to filing this, you read this paragraph and understood it at the time?

A. I'm sure I did.

Q. Did you consider at all disclosing, together with the '341 patent, which is just prior to this -- well, I represent to you that you did in fact in this '331 application call out the '341

patent, OK, portions of it, correct?

A. Yes.

THE COURT: You have already testified to that, right, the '341 was mentioned in the '331.

THE WITNESS: Yes.

Q. You didn't specifically call out the Tmax of 2 to 4, the hydromorphone, correct?

THE COURT: He has already said that.

A. No.

Q. Now I will ask you the same question. Did you consider calling out the '984 patent to the examiner in similar disclosure of the Tmax of 2 to 4 for dihydrocodeine?

A. No.

Q. You have no recollection of making that consideration?

A. I'm sure I made the consideration and decided against it.

Q. Did you decide against making that disclosure together with any of the co-inventors?

A. I don't understand the question.

Q. In making the decision not to cite to the '984 patent, was that your decision alone?

A. My decision.

Q. Now I ask you whether you recollect discussing that, for example, with any of the co-inventors.

A. No recollection.

Q. Do you recall discussing it with Mr. Paul Goldenheim?

A. No.

Q. Can we now turn to page that has on the bottom EN205613. Do you recall that there came a time when the claims as presented in the application were rejected over the prior art?

A. Yes.

Q. Do you recall that that prior art was former art of Purdue, that is, the '598 patent and the '341 patent?

A. Yes.

Q. This was Examiner Spear that was involved at this, correct? His name appears here. I don't think we have to focus in on it, but it was Examiner Spear?

A. Yes.

Q. Can we now jump to page 205617. This is a response to an official action dated October 22, 1992. Do you see that?

A. Yes.

Q. A response to an official action is Purdue's response to the rejection, among other things, based upon the '341 and the '598, is that correct?

A. Correct.

Q. You will see, if we turn to page 621, at the end, that Mr. Davidson has now signed on behalf of your firm.

A. Yes.

Q. It appears that this is the first time his name appears on the '331 patent?

A. Correct.

the prior art would show.

Q. Did the prior art at this time, to your knowledge, show a substantially narrower, reduced dosage range?

A. For oxycodone?

Q. No. Oxycodone was the invention, is that correct?

A. Right.

Q. My question is, in the prior art as of this time did you find a substantially narrower dosage range for oxycodone?

A. Not for oxycodone, no

Q. Did you find quicker titration for other prior art formulations?

A. I don't remember that.

THE COURT: Let me give you a hypothetical, sir. It may be unfair. If it is, just tell me.

Assume that I am making a patent application for a soapbox racer. The kids put together a soapbox racer, at least they used to. I describe how the racer should be put together. It has a wooden side and it has two axles, or in this case it has three axles. I say in the application that the unexpected results of this invention were that the soapbox racer went faster than any other soapbox racer or it went uphill instead of downhill -- it doesn't matter. The examiner, in an interview -- because my patent attorney went to him and said here is an invention, it is soapbox racer with three axles and we had unexpected results, it goes uphill instead of downhill

even though it doesn't have a motor -- said, well, I should have some proof as to what those unexpected results were, and he writes on this form "applicant will submit unexpected results."

Can you fit that into what you said? It seems to me that he would be asking for some test results that showed it went uphill.

THE WITNESS: In the case where it is a past tense situation that it goes, then you have to have proof by comparative tests. But that is not necessarily the case here. Here it is predictions as to what will occur.

THE COURT: Let me change the hypothetical then. That is, I write in the patent application that this is my invention, three axles, and unexpectedly it goes uphill. Are you saying that is a statement that it actually works and therefore there should be test results?

THE WITNESS: I really can't answer that question.

THE COURT: All right.

MR. FILARDI: I have nothing further, your Honor.

THE COURT: Anything?

MR. GOLDMAN: Yes, a couple, your Honor.

THE COURT: Yes, sir.

Excuse me. Here is the question. Again, if it is not answerable --

How does one distinguish between a claim that is

theoretical and one that purports to set forth proven test results?

MR. GOLDMAN: Your Honor, I think I can help with my --

MR. FILARDI: Objection, your Honor.

THE COURT: Just a moment, counsel. Wait. We have three things going. Hold that thought, sir.

I will let Mr. Goldman ask it, and then I will come back if I think it is necessary. Go ahead.

CROSS-EXAMINATION

BY MR. GOLDMAN:

Q. Mr. Steinberg, do you have the '331 file history there, sir, in the book in front of you?

MR. FILARDI: It is DX-2008.

Q. DX-2008. It is the first tab in the book.

A. I don't find it.

Q. It is the first tab in the book?

A. Yes, I have that. That is 2008?

Q. Yes, sir.

A. That is hydromorphone.

Q. No, sir.

A. Oh, oxycodone.

THE COURT: It is the '331.

A. Yes.

Q. Can you turn, please, to page EN205604.

A. Yes.

Q. That was the claimed invention, sir, is that right?

A. Correct.

Q. Is there a relation between what is claimed and the so-called unexpected results, as you understand patent procedure?

A. Yes, there is a relation.

Q. Can you explain to the Court what the unexpected results needed to relate to, as you understood it.

A. The unexpected results occur when you have the in vivo 2 to 4 hours after administration, you get a longer -- I don't see it in the claim there, but the result is that it is a longer period of action.

Q. Is there a statement anywhere in the claim of the '331 patent relating to the reduction in the range of dosages?

A. I don't remember. Let me look.

Q. The claim is on the page I referred you to. I don't know where else you want to look at. It is on page 205604.

A. Yes. I believe, I'm not that familiar any longer, that you have a peak plasma level between 2 and 4 hours after administration.

Q. What is the subject of the claim? Let's just go through the claim. What does the claim call for?

A. A controlled-release oral dosage form with an analgesically effective amount of oxycodone.

Q. Then the claim goes on to describe what?

A. It describes the dissolution rate of the matrix and the release rate, the time of the release rate.

Q. As you understood the rejection over the prior art, what was the examiner comparing? Let me put it this way. Did the examiner compare the prior art to the claim or to something else?

A. He to compare it to the claim.

MR. FILARDI: Objection, your Honor.

THE COURT: I will allow it.

A. He had to compare it to the claim.

THE COURT: That is your assumption?

THE WITNESS: Yes.

THE COURT: All right.

MR. GOLDMAN: I think that is all I have on this point, your Honor. Does that answer your question?

THE COURT: Let me phrase it my way. Again, if you can't answer it, you can't. How does a patent examiner distinguish between a claim that is simply a theoretical invention and one in which there are test results?

THE WITNESS: I don't know.

THE COURT: All right.

Mr. Filardi, anything?

MR. GOLDMAN: I just have one other question.

THE COURT: I thought you were done. I'm sorry.

MR. GOLDMAN: No, your Honor. That was just on that subject. I have one other question on redirect.

THE COURT: I'm sorry. I thought you were finished and saying I could go back. Go ahead.

BY MR. GOLDMAN:

Q. Mr. Steinberg, you testified on direct that you decided not to cite the dihydrocodeine art in the '331 case.

A. Correct.

Q. Do you recall why you did that?

A. Because it was cumulative, and hydromorphone was the most closely related.

MR. GOLDMAN: I have no further questions.

THE COURT: Mr. Filardi, anything?

MR. FILARDI: Just one thing on that last question. Maybe we can do it without an exhibit.

REDIRECT EXAMINATION

BY MR. FILARDI:

Q. The statement was made in the application "it is usual in the art," do you recall that?

A. Yes.

Q. To have T-4 to 8, right?

A. Correct.

Q. With that in mind, you did not cite the '984 patent, isn't that correct?

A. Which is the '984? The dihydrocodeine?

Q. Correct, one you didn't cite.

A. That's correct.

Q. Or anything else that you knew about that had 2 to 4 in the prior art?

MR. GOLDMAN: I object to the question as being a fragment.

THE COURT: Rephrase it.

Q. You didn't cite anything else in the prior art --

A. No.

Q. -- correct, the record shows this, that demonstrated that it was not usual in the prior art, particularly with regard to opioid analgesics, to have T-2 to 4?

A. No. We are talking about oxycodone, not opioid analgesics in general.

Q. The statement "it is usual in the art to have T-4 to 8," did that relate to oxycodone?

A. Oxycodone.

Q. That is your understanding?

A. Yes.

MR. FILARDI: No further questions, your Honor.

THE COURT: Let me ask my question in a slightly different way and see if it helps. Again, if it can't be answered, sir -- I am just trying to see what your view is.

How does a patent examiner distinguish between a theoretical claim and one that purports to set forth proven

A. Good afternoon.

Q. Are you currently practicing patent law?

A. Yes.

Q. And could you just tell us a little bit about your background. How long have you been practicing patent law?

A. I have been practicing patent law since 1986.

Q. And you were formerly with the firm of Steinberg & Raskin?

A. That is correct.

Q. Which eventually became Steinberg, Raskin & Davidson?

A. That's correct.

Q. What is the name of your current firm?

A. Davidson, Davidson & Kappel.

Q. Would I be correct in stating that during the period of time from 1986, when you joined the Steinberg firm, to the current time, the focus of your practice has been in the prosecution of patent applications?

A. No.

Q. How about in the period of time when you were with the Steinberg firm, from 1986 through, say, 1994?

A. I wasn't with the Steinberg firm in 1986.

Q. Ah. You joined the Steinberg firm, forgive me, in March of 1991?

A. Correct.

Q. During the period 1991 to 1997 with the Steinberg firm, would I be correct in stating that a significant portion of

your practice was involved with the prosecution of patent applications?

A. A significant portion was patent practice, yes.

Q. And are you currently registered as a patent agent or patent attorney with the United States patent office?

A. Yes.

Q. When did you first obtain your registration?

A. 1987.

Q. And is your registration currently in force?

A. Yes.

Q. Would I be correct in stating that you practiced as a registered patent attorney specifically during the period 1991 to 1997?

A. Yes.

Q. And during that period of time, were you familiar, thoroughly familiar with the patent statute and its provisions?

A. Yes.

Q. Same for the Code of Federal Regulations, the Rules of Patent Practice and Procedure?

A. Yes.

Q. As well as the manual of patent examining procedure?

A. To the extent I need to be, yes.

Q. And how about rule 56, the duty of candor, were you familiar with that rule and its provisions throughout that period 1991 through 1997?

A. Yes.

Q. And did you abide by that rule in your practice?

A. Yes.

Q. And did you advise inventors and co-inventors of their obligations under that rule?

A. Yes.

Q. As well as clients, in other words, individuals who worked for your clients who did certain work in connection with patent applications, did you advise them of their duty?

A. Yes.

Q. Now, you are familiar -- are you familiar with the subject matter of this litigation, the patents, the '912, the '042 and the '295?

A. Yes.

Q. And are you familiar enough with those patents to know that the '912 patent has the same disclosure as the '042 and the '295?

A. Yes.

Q. And would I be correct in stating that you prepared and filed and prosecuted the '912 patent?

A. That's correct.

Q. As well as the '042 and the '295?

A. Yes.

MR. FILARDI: Could we please have Defendant's Exhibit 2033, which is the file history of the '912 patent in suit?

Your Honor, may I say for the record that during the examination of Dr. Kaiko, I used Defendant's Exhibit 2075. It is the same document. This one is a bit clearer in copy, and I am using this one as well. But I have checked it and it has the same pages, although not the same production numbers at the bottom.

BY MR. FILARDI:

Q. Let me take you directly -- just as an overview, do you recall that during the course of this patent that a rejection was made in view of the prior art?

A. Yes.

Q. Do you recall that there came a time -- and I will show this to you right now. Can we go to page P000175. There came a time when, in response to a rejection by the examiner, you on behalf of Purdue filed an amendment or response to that official action. Do you recall that?

A. Yes.

Q. And can we take a look at the upper portion here, just so we see what information is provided on top. Just the top portion, please.

So just that we all understand, this says "amendment," but sometimes they are called "response." Would I be correct in saying that an amendment may deal with amending the specification of the claims in some way and includes a response?